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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,064	10/31/2001	Carolyn Elizabeth Lister	01288.0016	4565

7590 12/17/2002
Finnegan Henderson Farabow Garret & Dunner
1300 I Street NW
Washington, DC 20005

EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,064

Applicant(s)

LISTER ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Status of the Claims

1. Claims 1-15 are pending and are examined in the instant application.

Specification

2. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 4, dated 13 November 2001, is attached to the instant Office action.

Claim Rejections - 35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, (a) "delivering previously manipulated DNA into embryo or embryo-derived culture cell types" is unclear because the DNA is being delivered to cells, not cell types. This could be clarified by inserting "cells" after "embryo" and changing "cell types" to "cells. Also "delivering....DNA ...of the Allium

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genus” needs to be changed to say “plant” because the DNA is being delivered to cells of a plant, not of a genus. It is also unclear what is intended by “previously manipulated”. Suggested language is “delivering DNA into embryo cells or embryo-derived cultured cells of an *Allium* genus plant”. All subsequent recitations of this language is also rejected.

“Vector” needs an “a” in front of it.

- In 1(b), “transformed plant material” lacks antecedent basis;
- In 1(c) “the transformed plants” lacks antecedent basis.

In claim 3, “the plants” lacks antecedent basis.

In claim 5, “inoculated” with what? To what does “their “ refer? “isolated” from what?

In claim 7, (b) “cultures” lacks antecedent basis; a step seems to be missing here.

- In claim 7 (c) “embryos” lacks antecedent basis.
- In 7(e) “embryo pieces” lacks antecedent basis.
- In claim 8, “gene” is unclear because a “gene” implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant’s intention, the language “a DNA of interest” is suggested. Or Applicant may recite the various components of the “gene” desired.

In claims 13 and 15, what does "modified" mean" with regards to an alliinase gene?

6. Claims 4-6 and 8-15 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim depends on another multiple depended claim.

See MPEP § 608.01(n).

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 13, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transformed onion plants produced by the method of delivering DNA by vector or direct gene transfer, selecting transformed plant material and culturing and regenerating transformed onion plants, does not reasonably provide enablement for a plant transformed with a modified alliinase gene, or for a plant containing a modified gene involved in the sulfur pathway which results in altered levels of sulfur compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The enablement issues are “a modified alliinase” and “a modified gene involved in sulfur pathway assimilation or breakdown and as a result has altered levels of sulfur compounds”.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)):

Nature of the invention. The claims are drawn to method of transforming allium plants, using vectored or direct gene transfer of embryo or embryo-derived tissue; transformed plants produced by this se methods. And to the method where the plant is transformed with a modified alliinase gene. And to a transformed plant produced by the methods where the plant contains a modified gene involved in sulfur pathway assimilation or breakdown and as a result has altered levels of sulphur compounds.

State of the prior art. The state of the art is such that the skilled person can introduce a gene into plant cells, and given the appropriate regulatory signals and substrates, have a reasonable expectation of expressing the gene in transgenic plant tissue. However, the skilled person would not be able to introduce a “modified gene” or a “modified alliinase” into cells of a plant, without guidance as to the nature of the “modification”. What is “modified”? Is it a coding sequence, a regulatory sequence? Or does the modification involve coding sequences? Or regulatory sequences, or both? Is the modification a mutation? Does the modification involve insertions, or deletions, or rearrangements or combinations of these? Or is it a second-site regulatory mutant?

Breadth of the claims. The claims are drawn to methods of transforming allium plants, using vectored or direct gene transfer of embryo or embryo-derived tissue; transformed plants produced by these methods. And to the method where the plant is transformed with a modified alliinase gene. And to a transformed plant produced by the methods where the plant contains a modified gene involved in sulfur pathway

Working examples. There are no working examples of any modified alliinase or any modified gene resulting in altered levels of sulfur compounds.

Guidance in the specification & Predictability of the art. The physiological art in general is acknowledged to be unpredictable (MPEP 2164.03). The art is such that the skilled person can introduce genes into plant cells but that transformation with a “modified” gene or “modified alliinase to produce a transformed plant containing a modified gene involved in sulfur pathways so as to result in altered levels of sulfur compounds”, without guidance as to what modifications to make to have the desired effect, would require undue experimentation. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

In view of the breadth of the claims (any modification, a modified gene, modified alliinase, any alteration of sulfur compounds), the lack of guidance in the specification,

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the unpredictability of the art, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1- 4, 6, and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bidney (EP0486234, published 20 May 1992).

Bidney teaches a method of transforming Allium plants comprising delivering previously manipulated DNA into embryos (page 4, line 12) via a binary vector (p 4, line 30), selecting transformed material (p 6, line 42), and culturing and regenerating transformed plants (p 3, line 9). Bidney further teaches the method using Agrobacterium (p 4, lines 16-32), onions (p 4, line 1), the use of immature embryos (p 4, line 10), Agrobacterium having a selectable marker (p 3, lines 23-29), herbicide resistance gene (p 3, 25-29), bar resistance, an antibiotic resistance gene and a nptII gene (p3 line 25).

Accordingly, Bidney anticipates the claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bidney (EP0486234, published 20 May 1992).

Bidney teaches a method of transforming *Allium* plants comprising delivering previously manipulated DNA into embryos (page 4, line 12) via a binary vector (p 4, line 30), selecting transformed material (p 6, line 42), and culturing and regenerating transformed plants (p 3, line 9). Bidney further teaches the method using *Agrobacterium* (p 4, lines 16-32), onions (p 4, line 1), the use of immature embryos (p 4, line 10), *Agrobacterium* having a selectable marker (p 3, lines 23-29), herbicide resistance gene (p 3, 25-29), bar resistance, an antibiotic resistance gene and a nptII gene (p3 line 25). Bidney does not teach a method where embryos are inoculated immediately following their isolation. One of ordinary skill in the art would have been motivated to use embryos immediately after their isolation, because this would shorten the time needed for the overall process, and would make the process faster.

Accordingly, the claimed invention is *prima facie* obvious in view of the prior art.

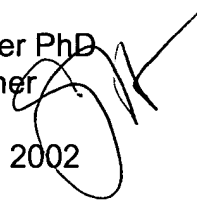
Remarks

13. No claim is allowed.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner
Art Unit 1638
December 13, 2002



ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800